Healthcare Identifiers Software

Conformance Assessment Scheme

Version 3.0 — 3 May 2011

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Document Control

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Document information

Revision history

Version	Date	Comments
0.1	02/11/09	Initial draft for internal review.
0.2	10/12/09	Modifications to describe the preferred testing process.
0.3	15/12/09	Incorporated feedback from the first internal NEHTA review.
0.4	20/01/10	Incorporated feedback from a second internal NEHTA review.
1.0	08/11/10	Updated to refer to the conformance requirements for health software systems' use of healthcare identifiers. Changes made to the assessment process diagram. A reference to the E-Health Register was added.
1.1	13/12/2010	Updated to refer to Medicare Australia's NOI process.
1.2	07/2/2011	Added clarification to many sections after receiving stakeholder feedback
1.3	17/2/2011	Updated to reflect feedback from Medicare Australia
1.4	28/02/2011	Minor corrections
1.5	10/03/2011	Changes following consultation with ICP and CCA working groups via teleconference.
2.0	31/3/2011	Final version, incorporating feedback from public comments.
2.1	8/04/2011	Incorporated feedback from the eHealth CCA Governance Committee
2.2	20/04/2011	The process of declaring conformance was modified.
3.0	03/05/2011	Approved version.

Executive Summary

NEHTA in consultation with the health sector including Medicare Australia, the Department of Health and Ageing, the Medical Software Industry Association (MSIA), the Australian Information Industry Association (AIIA), the Aged Care IT Vendors Association (ACIVA), state and territory health departments, has developed conformance requirements and an assessment process to support the safe use of healthcare identifiers by health software systems.

The Healthcare Identifiers Service was developed to assign, issue and maintain national healthcare identifiers for consumers and providers. The healthcare identifiers enable health software systems to associate health information about a healthcare recipient accurately, securely and consistently within a healthcare context.

Software systems requiring direct access to the HI Service must complete both HI conformance testing (as documented in this HI Conformance Assessment Scheme) and Medicare Australia's Notice of Connection (NOC) testing process. The conformance testing described in this document are often referred to as the 'CCA' tests. The CCA tests performed to assure the safe use of healthcare identifiers by a health software system and the NOC tests are performed to determine that the software can connect to the HI Service.

This first phase of the healthcare identifiers conformance requirements apply to software systems that directly access the healthcare identifiers (HI) Service. For software systems that do not directly access the HI Service, but manage and use local copies of healthcare identifiers, it is strongly recommended that these systems still undergo HI conformance testing in order to support the correct handling of identifiers.

The HI Conformance Assessment Scheme and associated test specifications aim to define consistent testing of health software systems that provides a sufficient assurance of conformance to the software requirements for use of healthcare identifiers.

Correct handling and use of healthcare identifiers by software systems will improve efficiency and quality of healthcare and reduce errors in managing patient information. Conversely, clinical safety risks may arise from incorrect or inappropriate use of healthcare identifiers.

Due to the significance of these risks, health software systems are to be assessed for conformance to requirements for the use of healthcare identifiers. The health software sector and the Department of Health and Ageing have agreed independent testing is to be mandated for new or significantly changed compliant systems to assure safe use of identifiers.

This testing is to be conducted by test laboratories that have been accredited by the National Association of Testing Authorities (NATA) to perform HI testing. These laboratories are independent organisations that understand the risks associated with incorrect use of healthcare identifiers and perform tests to reduce these risks. Test laboratories can perform testing at the premises of a software developer and can also perform testing in their own test environment.

The healthcare identifiers conformance test specifications contain a set of conformance test cases derived from conformance requirements for the use of healthcare identifiers. Test cases are grouped by business use case. Conformance test specifications have both positive and negative functional test cases, to detect incorrect behaviour and ensure wrong data is handled correctly.

1 Introduction

1.1 Document purpose

This document describes the scheme for assessing the conformance of health software systems to requirements for the use of healthcare identifiers (referred to here as the HI software conformance requirements).

1.2 Scope

The scope of HI conformance assessment is to test the conformance to the HI software conformance requirements of health software that will directly access the HI Service.

The scope does not include testing conformance to the HI software conformance requirements of health software that manages healthcare identifiers but does not directly access the HI Service. This may be included within the scope of the document in future.

It is strongly recommended that systems that do not directly access the HI Service still undergo conformance assessment to ensure their product uses and manages healthcare identifiers in a manner that supports clinical safety, security and privacy.

Correct handling of healthcare identifiers by health software systems will assist in the reduction of errors and increase efficiency in managing patient information, potentially leading to improvements in the quality of patient healthcare.

A second phase of development of the HI conformance assessment scheme will include the following items:

1. Conformance requirements and testing for health software that manages and uses healthcare identifiers but does not directly access the HI Service; and
2. Approach to retesting (when a new version of health software is issued by a developer; when the HI software conformance requirements are updated, when NOC tests are repeated and when the HI Service is updated).

1.3 Intended audience

The intended audience includes:

- Developers of health software that use healthcare identifiers;
- Operators and owners of e-health services that use healthcare identifiers;
- Health departments, healthcare providers and systems integrators that implement software systems that use healthcare identifiers; and
- Software test laboratories.

In this document, a ‘developer’ is any organisation that develops a health software system that manages and uses healthcare identifiers.

1.4 Acknowledgements

Contributions to this document is acknowledged by NEHTA. Members of the healthcare identifiers working group include Medicare Australia, the Department of Health and Ageing, the Medical Software Industry Association, the Australian Information Industry Association, Aged Care IT Vendors Association, the Tasmanian Department of Health and Human Services, the Victorian Department of Health, the ACT Department of Health and the NT Department of Health. Contributors during the public comment period include other health jurisdictions, vendors and government authorities.

1.5 Contact details

Any comments or feedback should be sent to the NEHTA Compliance, Conformance and Accreditation unit: **cca@nehta.gov.au**.

2 Abbreviations and terminology

Conformance	A determination (by testing) of the adherence of an implementation to a specification or standard.
Conformance requirement	A technical requirement in a specification to be supported by a developer's implementation.
Developer	An organisation that develops a health software system using the HI software conformance requirements.
HI	Healthcare Identifier: an identifier assigned to a healthcare provider (individual or organisation) or a healthcare recipient as defined in the Healthcare Identifiers Act [HIACT2010].
ICS	Implementation Conformance Statement.
HI implementation	A health software system that manages and uses local copies of healthcare identifiers.
NATA	National Association of Testing Authorities. NATA is Australia's national authority for accrediting test laboratories.
NOC	Notice Of Connection. The term 'NOC' refers to Medicare Australia's testing process to determine health software can connect to the HI Service.
Object of assessment	A health software system or service, or a component of a health software system or service, which is assessed for conformance.
Test Summary Report	Documents the results of tests performed by a test laboratory on behalf of a developer.

3 Requirements for HI conformance assessment

3.1 The approach to conformance testing

HI software conformance requirements [NEHTA2011a] have been created to help software developers develop health software that:

- Minimises risks to clinical safety, privacy and information security;
- Implements good practice in the acquisition, use and disclosure of healthcare identifiers;
- Assists healthcare providers to comply with the *Healthcare Identifiers Act 2010* [HIACT2010] and the Healthcare Identifiers Regulations 2010 [HIREGS2010]; and
- Achieves the expected benefits of using healthcare identifiers.

Correct use of the HI Service's Individual Healthcare Identifiers (IHIs) will improve the efficiency and quality of health care. The adoption of IHIs by healthcare providers with the support of software systems will help to address the management of disparate patient information. Conversely, HI implementations that do not properly manage and use local copies of individual healthcare identifiers may pose a risk to clinical safety and fail to realise the full benefits of using the HI Service's IHIs.

When healthcare identifiers are incorrectly managed:

- A healthcare recipient may be misidentified (e.g. due to transcription errors in manually entered identifiers);
- More than one healthcare identifier may exist for the same healthcare recipient; and
- The same identifier may be associated with records of more than one healthcare recipient.

Associating the wrong health information to a healthcare recipient can jeopardise clinical safety, through the introduction of errors such as:

- Medication errors;
- Incorrect surgical interventions; and
- Diagnostic testing errors.

To mitigate these risks and achieve the benefits of using the HI Service's IHIs:

- Conformance tests are derived from HI conformance requirements;
- Conformance tests include both positive and negative functional test cases to ensure that wrong behaviour or wrong data is handled correctly; and
- Software conformance testing is to be performed by NATA accredited, independent test laboratories that have incorporated HI into their scope of testing.

Health software vendor representatives, the Department of Health and Ageing and Medicare Australia have agreed that testing must be performed by NATA accredited test laboratories who have added HI conformance to their scope to ensure that identified risks for the clinically-safe use of identifiers are properly addressed. The use of NATA accredited test laboratories ensures Australian and international testing standards are applied in a consistent manner.

3.2 Organisations that participate in HI conformance assessment

Organisations that participate in HI conformance assessment are listed in Table 3.1.

Organisation	Roles
Developer	An organisation that creates a HI implementation using HI conformance requirements.
Test laboratory	An independent assessor of conformance to HI conformance requirements.

Table 3.1: Roles and organisations in HI conformance assessment

3.3 Test laboratory accreditation

To recognise conformance of a HI implementation, an independent assessment of conformance must be performed by a test laboratory with the following NATA accreditations (www.nata.asn.au):

1. General requirements for testing laboratories [ISO17025]; and
2. Specific accreditation for testing HI implementations for conformance to HI software conformance requirements using the process described in this document. This is subclass 22.40.02 of NATA's '22.40 Healthcare Tests' accreditation.

Test laboratory accreditation uses criteria and procedures specifically developed to determine technical competence. NATA accreditation is a formal recognition of the competence of a test laboratory's ability to perform testing of health software systems that manage and apply healthcare identifiers. Use of accredited laboratories provides assurance of consistent testing according to the HI conformance assessment scheme.

3.4 Relevant technical requirements

Detailed conformance requirements are listed in the following requirements:

- Use of Healthcare Identifiers in Health Information Systems: Software Conformance Requirements [NEHTA2011a]. It is proposed that this NEHTA document be submitted to the Standards Australia IT-014 work group program for 2011/2012 with a view to creating an Australian Technical Specification.

3.5 Conformance requirements

Conformance requirements are defined for a set of business use cases that describe the usage of healthcare identifiers by health software [NEHTA2011d]. To determine which conformance requirements apply to a health software implementation, a developer first identifies the business use cases that apply to their HI implementation. Once these are known, the conformance requirements corresponding to the relevant business use cases are identified [NEHTA2011a]. Support for some of the conformance requirements is mandatory for the selected business use cases while others are recommended.

Business use cases are described in terms of business process models to illustrate the workflow, tasks and decisions for each business use case. They are intended to be generic and applicable to any healthcare setting. Aspects of a business use case that must be supported by HI implementations are explicitly stated as HI conformance requirements.

HI implementations must conform to the conformance requirements of business use cases they support and not implement any prohibited capabilities for these business use cases.

3.6 Medicare Australia's testing requirements for the HI Service interface

A health software system may obtain access to the HI Service either:

- Directly, through web services that access the HI Service interface; or
- Indirectly, through third-party software that accesses the HI Service.

To implement web services for the HI Service, Medicare Australia's Licensed Material should be used. The HI Service Licensed Material contains information for developers such as the HI Service System Interface Specifications [HISIS], HI Service Developers Guide, Web Services Description Language definitions and XML Schema definitions. The Licensed Material may be obtained when developers accept the terms and conditions of the Licence Agreement - Use of the Healthcare Identifiers Licensed Material for Notice of Connection.

Medicare Australia manages the Notice of Connection (NOC) testing process. The NOC tests that a software system can connect to the HI Service. Medicare Australia does not charge developers to test for a NOC.

NOC testing is performed independently to the HI conformance tests. The HI conformance tests are performed to assure the safe use of healthcare identifiers by a health software system and the NOC tests are performed to determine that software can connect to the HI Service.

NOC testing and HI conformance testing may be performed in any order although it is recommended that NOC testing is performed first.

Further information in regards to the Licensed Material and NOC testing process may be obtained from the Medicare Australia website:

www.medicareaustralia.gov.au > For health professionals > For software vendors

3.7 Medicare Australia's vendor environment

Medicare Australia's vendor environment allows developers to develop and test their HI implementations to ensure they will connect to the HI Service. Medicare Australia's NOC testing is also performed in the vendor environment.

Access to the vendor environment is given to developers once they have accepted the terms and conditions of the Licence Agreement - Use of the Healthcare Identifiers Licensed Material for Notice of Connection. Test data for the HI Service web services will be given to developers to assist with transmissions into the vendor environment.

The vendor environment is a shared by other developers doing business for other Medicare Australia online programs. Medicare Australia does not charge developers for use of the vendor environment.

Further information can be obtained from the Medicare Australia website:

www.medicareaustralia.gov.au > For health professionals > For software vendors

4 Conformance assessment process

This section describes the process for assessing the conformance of a HI implementation to the software requirements for the use of healthcare identifiers.

4.1 HI conformance assessment

HI conformance assessment tasks are illustrated in Figure 4.1.

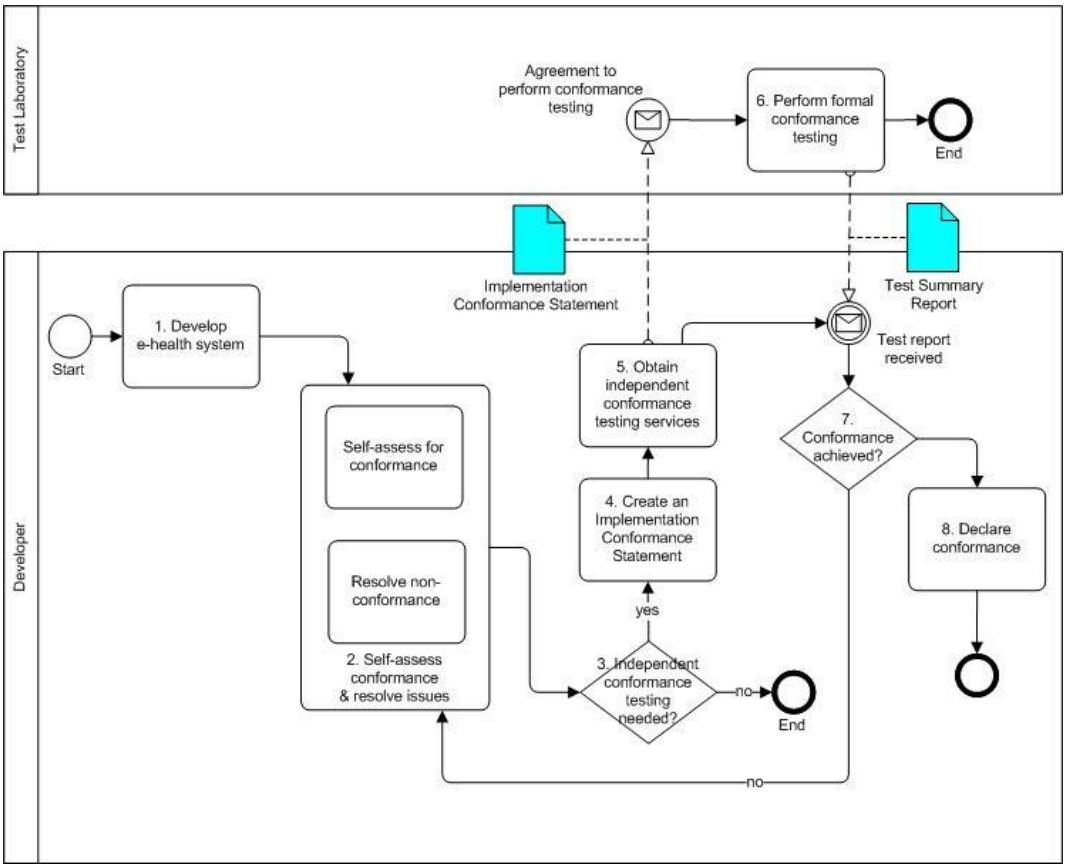

Figure 4.1: Conformance assessment process

HI conformance testing tasks are described in Table 4.1, including decisions on whether some of these tasks need to be performed.

	Process Item	Type	Description
1	Develop e-health system	Task	The developer creates, or modifies, a health system that uses healthcare identifiers.
2	Self-assess conformance & resolve issues	Task	Once a HI implementation has been created or modified to support the HI conformance requirements, the developer may perform their own assessment of the HI implementation's conformance to these requirements. Conformance test documentation describes the tests to be applied (see section 4.3).

3	Independent conformance testing needed?	Decision	The HI implementation must be submitted to a test laboratory for an independent assessment of conformance, if any of the following is true (see section 5.1): • The HI implementation has not previously been declared conformant; • A new version of the HI implementation has been created that affects the implementation's conformance to the HI software requirements; • A previous version of the HI implementation has been declared conformant but the developer has subsequently enhanced the HI implementation to support additional business use cases or conformance requirements and wants to claim conformance for these; • A new version of the HI conformance requirements has been issued and the developer wants to claim conformance to this new version; or • A new version of the HI implementation has been created with changes to software components that access and/or manage healthcare identifiers.
4	Create an Implementation Conformance Statement	Task	The developer creates an Implementation Conformance Statement to indicate the conformance requirements supported by their HI implementation (see section 4.2).
5	Obtain independent conformance testing services	Task	One or more organisations may be considered by the developer when choosing a test laboratory to independently test the conformance of a HI implementation. The test laboratory must be accredited to assess conformance (see section 3.3).
6	Perform formal conformance testing	Task	Formal conformance assessment is performed by an accredited test laboratory.
7	Conformance achieved?	Decision	The selected test laboratory will advise the developer whether their HI implementation conforms to HI conformance requirements.
8	Declare conformance	Task	The developer declares the conformance of the HI implementation (see section 4.6).

Table 4.1: HI conformance assessment tasks and decisions

4.2 Implementation Conformance Statements

To test the conformance of an health software system under test (referred to here as the implementation), a statement of its capabilities and options implemented may be needed. This is called an Implementation Conformance Statement (ICS).

An ICS:

- Enables a developer to precisely state the conformance requirements that are supported by a HI implementation;
- Is used in communications with a test laboratory and may be used in communication with potential purchasers of a HI implementation; and
- May be used by an organisation wanting to procure a HI implementation, to specify the features they require.

An ICS proforma for healthcare identifiers is provided for developers [NEHTA2011b]. The developer is responsible for describing their HI implementation in the ICS.

The ICS is used as follows:

1. The developer obtains an ICS proforma, along with instructions for completing the proforma;
2. The developer uses tables within the ICS to indicate which conformance requirements are supported by the HI implementation;
3. If formal conformance assessment is required, the developer sends the ICS to a test laboratory;
4. The test laboratory will only test those features that the developer includes in the ICS; and
5. The developer revises the ICS to only claim conformance to conformance requirements that the test laboratory has found to be supported by the HI implementation.

Email cca@nehta.gov.au for a copy of the ICS proforma for healthcare identifiers.

4.3 Conformance test specifications

The HI conformance test specifications [NEHTA2011c] provide details of tests to be performed when assessing conformance. The HI conformance test specifications contain test cases that translate conformance requirements into concise, self-contained tests with a clear objective and criteria for passing. A test case is a set of inputs, execution conditions and expected results that has been developed to verify that a developer has correctly implemented the conformance requirements.

The HI conformance test specification identifies one or more test cases for each conformance requirement. Test cases reference items in the proforma Implementation Conformance Statement, so that applicable test cases can be applied.

Email cca@nehta.gov.au for a copy of the HI conformance test specifications.

4.4 Success criteria

Criteria for successfully claiming conformance to the HI conformance requirements are:

1. The HI implementation must support the mandatory conformance requirements that correspond to the relevant business use cases (section 3.5);
2. A 100% pass rate is required for the test cases (section 4.3) corresponding to these conformance requirements; and
3. A 100% pass rate is required for all conformance tests for recommended conformance requirements for which a developer wants to claim conformance.

4.5 Conformance test reporting

A conformance test summary report must be produced by the test laboratory. The conformance test summary report must include:

1. The name of the organisation and person that performed the conformance tests;
2. Details of the organisation's accreditation to perform HI conformance testing;
3. The date on which the tests were performed;
4. The full suite of information required to identify the HI implementation tested for conformance, including the name and version number;
5. The names and versions of the conformance test specifications and tools used to perform the tests;
6. The version of the HI software conformance requirements to which the HI implementation conforms;
7. Information about the computing environment used to perform the tests, such as the operating system name and version;
8. The result of executing each test case for each conformance requirement that the developer claims to have implemented; and
9. A statement indicating if the HI implementation meets the conformance requirements for each supported business use case (section 3.5).

The conformance test summary report is issued by the test laboratory to the developer and copied to Medicare Australia. The copy sent to Medicare Australia is needed for the task of declaring conformance.

4.6 Declaring conformance

Prerequisites for declaring the conformance of a HI implementation are:

1. Conformance test success criteria must be met (section 4.4); and
2. Conformance testing must be performed by an accredited test laboratory.

The developer then declares the conformance of their health software system (the HI implementation) by submitting a HI declaration of conformity [NEHTA2011e] and supporting implementation conformance statement to Medicare Australia (HI.Vendor.Operations@MedicareAustralia.gov.au). The HI declaration of conformity and implementation conformance statement together form a developer's claim of conformance of their HI implementation.

Medicare Australia will receive the conformance test summary report from the test laboratory selected by the developer. Medicare Australia will examine the conformance test summary report to ensure it supports the developer's claim of conformance of their HI implementation.

Submission of a HI declaration of conformity and supporting documentation to Medicare Australia is proof of completion of the CCA tests and is mandated to obtain access to the HI Service. A health software system that requires access to the HI Service will be granted access only after the successful completion of both the HI conformance tests and the NOC tests.

The developer may optionally request that the HI implementation be listed in the Australian eHealth Register of Conformity. Listing the HI implementation in this register is a public declaration of the conformance. This process is under review by the eHealth CCA Governance Group.

5 Ongoing validity of conformance

5.1 Conformance and versioning

A developer may revise their HI implementation to create a new version, including:

- A major version, which may contain significant new functionality compared to the preceding version;
- A minor version, which may contain incremental additional functionality compared to the preceding version; and
- A maintenance version, which may correct one or more defects in a previously issued version.

Regardless of whether a new version is major, minor or a maintenance version, the new version must be submitted to an accredited test laboratory for formal conformance testing if:

- A conforming system is enhanced to support business use cases that were not supported by the preceding version of the system e.g. a system that was tested without merging capability has been expanded to now include merging capability.

  The new version will require conformance testing against every applicable conformance requirement associated with that business use case(s).

- A conforming system is enhanced to include sub-sections of business use cases that were not tested in the conforming version of the system e.g. a system that was tested without the capability to store unverified IHIs is expanded to include the capability to store unverified IHIs.

  The new version will require conformance testing against every applicable conformance requirement associated with the whole business use case(s).

- A conforming system is modified so its existing support for HI software conformance requirements may be impacted e.g. a system that was tested with the capability to merge patient demographic data has been modified to use a different merge technique.

  The new version will require conformance testing against every applicable conformance requirement associated with the whole business use case(s).

- A new version of the HI implementation has been created with changes to software components that access and manage healthcare identifiers.

  The new version will need to be retested for conformance to the HI requirements for the supported business use case(s).

A developer may submit their HI implementation for formal conformance testing regardless of the scope of the revision.

5.2 Conformance and version of the HI software conformance requirements

If a version of the HI software conformance requirements (i.e. this document) is superseded by a new version, an HI implementation that has been declared conformant must conform to the new version twelve (12) months after the date of publication of the new version of the HI software conformance requirements. Note this does not replace the need to reassess conformance if an HI implementation is modified (section 5.1).

5.3 Validity period

A health software system's declaration of conformance to the HI software conformance requirements has no expiry date. The declaration only applies to the version of the HI implementation, and the version of the HI software conformance requirements, identified in the declaration of conformance.

If a health software system needs to be resubmitted to the NOC testing process the vendor should review whether the software should be retested and their declaration of conformity reissued.

Appendix A : References

This appendix lists documents that provide information for or about this document. At the time of publication, the document versions listed below were valid. However, as all documents are subject to revision, readers are encouraged to use the most recent versions of these documents.

[HIACT2010] Healthcare Identifiers Act 2010.

[HIREGS2010] Healthcare Identifiers Regulations 2010.

[HISIS] Healthcare Identifiers Service System Interface Specifications, Medicare Australia, 2010.

[NEHTA2011a] Use of Healthcare Identifiers in Health Information Systems: Software Conformance Requirements, version 1.4, NEHTA, 2011.

[NEHTA2011b] HI Implementation Conformance Statement Proforma, version 1.1, NEHTA, 2011.

[NEHTA2011c] Use of Healthcare Identifiers in Health Information Systems: Conformance Test Specifications, version 1.0, NEHTA, 2011.

[NEHTA2011d] Healthcare Identifiers - Business Use Cases, NEHTA, 2011

[NEHTA2011e] Healthcare Identifiers – Declaration of Conformity, NEHTA, 2011